DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 6 2012

Re: NATROBA
Patent Nos. 6,063,771 and 6,342,482
Docket Nos.: FDA-2011-E-0371
and FDA-2011-E-0379

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 6,063,771 and 6,342,482, filed by Eli Lilly and Company, under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for NATROBA (spinosad), the human drug product claimed by the patents.

The total length of the regulatory review period for NATROBA (spinosad) is 2,261 days. Of this time, 1,534 days occurred during the testing phase and 727 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 11, 2004.

   FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 11, 2004.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: January 22, 2009.

   FDA has verified the applicant's claim that the new drug application (NDA) for NATROBA (NDA 22-408) was submitted on January 22, 2009

3. The date the application was approved: January 18, 2011.

   FDA has verified the applicant's claim that NDA 22-408 was approved on January 18, 2011.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Jane A. Axelrad

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: James J. Sales
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